Date of IRB Review: May 2009
81st Medical Group
Keesler AFB, Mississippi

Exempt (Human) Research Protocol

This is a Progress Report ____ / Final Report _XX__

1. Protocol Number: FKE20070004E

2. Title: "Operative Findings and Demographic Characteristics of Chronic Pelvic Pain Patients in a Military Population"

3. Principal Investigator (PI): Andrew T. Allen, MD, Maj, USAF, MC, FS, 31 MSGS/SGCX, DSN 314-632-5863, andrew.allen@aviano.af.mil *(Add your rank and full name, squadron/office symbol, telephone number, beeper number)*

4. Purpose: *(Copy from your original protocol and paste here)* Chronic pelvic pain is non-menstrual pelvic pain of six or more months duration that is severe enough to cause functional disability or require medical or surgical treatment, with an estimated prevalence of 3.8% in women aged 15–73 in the general population. It is estimated to account for 10% of all referrals to gynecologists, and is the indication for 12% of all hysterectomies and over 40% of gynecologic diagnostic laparoscopies. Direct costs of health care for chronic pelvic pain in the United States are estimated at $880 million per year, and direct and indirect costs may total over two billion dollars per year.

The impact of chronic pelvic pain on military operations is potentially very significant. Active-duty women may miss important training opportunities as well as overseas deployments due to chronic pain; they may also eventually have to meet a medical board. If the patient is a dependent wife or daughter, the active duty member may be distracted with caring for his dependent at the expense of completing his duties. The purpose of this study was to identify demographic characteristics and findings at laparoscopy for chronic pelvic pain patients in a military population, and to compare those findings to an asymptomatic control group during the same time period that underwent laparoscopic tubal ligation.

This study was initiated at David Grant Medical Center (Protocol FDG2000019H). The primary outcome measures were obtained, however during sub-group analyses, we determined that the numbers were too small to assign significance. Therefore I am opening an identical study here at Keesler Medical Center, an institution of similar size and capability as David Grant Medical Center. This should approximately double the sample size and increase the validity and reproducibility of the findings.

This study will ultimately benefit the DOD/USAF in allowing OB/GYN physicians greater accuracy in counseling patients with chronic pelvic pain prior to surgery, and may provide better guidance in selecting those who would be better candidates for surgery. This could lead to a more cost-effective approach to surgical evaluation and management of this chronic condition.

5. Status of the Study. Mark the status of the study (a-e).

a. _____ Active with ongoing data collection. Request approval to remain open.

b. _____ Active with data collection complete. Request approval to remain open.

c. _____ Study was never initiated and request termination of the study.

d. ___XX__ Completed, research implemented and results available. Request approval to close.

e. _____ Inactive, protocol never initiated, but want to keep in open. Request approval to remain open.

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
28 SEP 2010	**Final Report**	**00-10-2006 to 00-05-2009**

4. TITLE AND SUBTITLE
Operative Findings and Demographic Characteristics of Chronic Pelvic Pain Patients in a Military Population

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Andrew Allen

5d. PROJECT NUMBER
FKE20070004E

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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8. PERFORMING ORGANIZATION REPORT NUMBER
FKE20070004E

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
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10. SPONSOR/MONITOR'S ACRONYM(S)
81MDG

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
FKE20070004E

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Chronic pelvic pain is non-menstrual pelvic pain of six or more months duration that is severe enough to cause functional disability or require medical or surgical treatment. It is estimated to account for 10% of all referrals to gynecologists, and is the indication for 12% of all hysterectomies and over 40% of gynecologic diagnostic laparoscopies. Direct costs of health care for chronic pelvic pain in the United States are estimated at $880 million per year, and direct and indirect costs may total over two billion dollars per year. The impact of chronic pelvic pain on military operations is potentially very significant. The purpose of this study was to identify demographic characteristics and findings at laparoscopy for chronic pelvic pain patients in a military population, and to compare those findings to an asymptomatic control group that underwent laparoscopic tubal ligation. The M2 data repository of standard inpatient data records was reviewed for all encounters associated with Diagnostic and Operative Laparoscopy and Laparoscopic Tubal Ligation. Four hundred and fourteen subjects met inclusion criteria and there were 237 control subjects. The pelvic pain group was more likely to have a medical history of pelvic inflammatory disease, headaches, depression, acid reflux disease and physical or sexual abuse.

15. SUBJECT TERMS
Chronic Pelvic Pain; M2; Military Medicine

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**1**	**4**	

6. Summary of Progress: This report covers the following period of time: October 2006 – May 2009. *Provide a brief summary of any results (preliminary or final) obtained in the study, even if results are not yet statistically significant.*

a. Since the initiation of study: Data collection is complete. Data analysis and paper write-up is in progress.

b. For the entire study: Completed

c. If this is a FINAL REPORT:

1. Were the protocol objectives met and how will the outcome benefit the DoD/USAF? *(Answer……)*

The objectives were met. This study will ultimately benefit the DOD/USAF in allowing OB/GYN physicians greater accuracy in counseling patients with chronic pelvic pain prior to surgery, and may provide better guidance in selecting those who would be better candidates for surgery. This could lead to a more cost-effective approach to surgical evaluation and management of this chronic condition.

2. Protocol Outcomes Summary: *(Please provide in abstract format a summary of the protocol objectives, materials, methods, and results. Include tables/figures, conclusions, and applications)*

Background: The impact of chronic pelvic pain on military operations is potentially very significant. Active-duty women may miss important training opportunities as well as overseas deployments due to chronic pain; they may also eventually have to meet a medical board. If the patient is a dependent wife or daughter, the active duty member may be distracted with caring for his dependent at the expense of completing his duties. The purpose of this study was to identify demographic characteristics and findings at laparoscopy for chronic pelvic pain patients in a military population, and to compare those findings to an asymptomatic control group during the same time period that underwent laparoscopic tubal ligation.

Methods: The M2 data repository of standard inpatient data records was reviewed for all encounters associated with Current Procedural Terminology (CPT) codes 49320, 49321, 49322, 49329, 58660, 58662, 58679, (diagnostic and operative laparoscopy) and 58671 (laparoscopic tubal ligation). Once subjects were identified, their charts were retrieved from medical records and variables were collected. Statistical analysis was performed with SPSS, version 14.0 (Chicago, IL, USA.)

Results: Four hundred and fourteen subjects met inclusion criteria. The mean age of our population with chronic pelvic pain was 29.2 years, compared to 32.2 years in the asymptomatic control group. There was a statistically significant difference between the 2 groups regarding age, parity, military status, which is primarily driven by the population of patients who undergo tubal sterilization. The pelvic pain group was more likely to have a medical history of pelvic inflammatory disease (OR 4.62, 1.48 – 14.41), headaches (OR 3.22, 1.53 – 6.7), depression (OR 2.27, 1.17 – 4.40), acid reflux disease (OR 3.73, 1.74 – 8.00), and physical or sexual abuse (OR 14.13, 1.79 – 111.45). Fifty-eight pain subjects had an operative diagnosis of endometriosis (classic visual signs), 35 (60.3%) of which had a peritoneal biopsy performed. Of those 35 biopsies, 19 (54.3%) had histologic features diagnostic of endometriosis and 3 (8.6%) had histologic features suggesting endometriosis. Of the 237 control subjects, 16 had an operative diagnosis of endometriosis, of which only 3 (18.8%) had biopsies performed. Of those 3 biopsies, 2 (66.7%) had histologic features diagnostic of endometriosis. Negative histologic diagnoses included endosalpingiosis, fibroadipose tissue, and fibromuscular tissue.

Table 1. Demographic characteristics.

	Pain (n=177)	No Pain (n=237)	Significance (P-value)
Age	29.2	32.2	*< 0.001*
Gravity	1.8	2.8	*0.057*
Parity	1.2	2.1	*<0.001*
Military Status (%)			*0.033*
Active Duty Military	67 (37.9)	89 (37.6)	
Dependent Wife	103 (58.2)	148 (62.4)	
Dependent Daughter	7 (3.9)	0 (0)	
Race (%)			*0.056*
Caucasian	123 (69.5)	133 (56.1)	
African American	19 (10.7)	47 (19.8)	
Hispanic	12 (6.8)	19 (8.0)	
Asian/Pacific Islander	4 (2.3)	5 (2.1)	
Unknown/Other	19 (10.7)	33 (14.0)	
BMI (%)			
<18.5 (underweight)	5 (2.8)	3 (1.3)	
18.5-24.9 (normal)	89 (50.3)	99 (41.8)	
25.0-29.9 (overweight)	49 (27.7)	82 (34.6)	
30.0 and above (obese)	34 (19.2)	53 (22.4)	

Table 2. Procedures

Procedure (%)	Pain (n=177)	No Pain (n=237)
Diagnostic only	74	n/a
Operative laparoscopy	103	n/a
Peritoneal biopsy	48 (27.1)	2 (0.8)
Ovarian cyst aspiration	4 (2.3)	1 (0.4)
Ovarian cystectomy	6 (3.4)	0
Ablation of endometriosis	19 (10.7)	1 (0.4)
Adhesiolysis	36 (20.3)	3 (1.3)
Chromopertubation	23 (13.0)	0
Cholecystectomy	1 (0.6)	0
Hysteroscopy	14 (7.9)	1 (0.4)
Endometrial ablation	0	2 (0.8)
Cystoscopy	19 (10.7)	0
Bladder biopsy	1 (0.6)	0
Appendectomy	12 (6.8)	0
LUNA	1 (0.6)	0
Bilateral tubal ligation[1]	8 (4.5)	237
Falope ring	6 (75.0)	178 (75.1)
Bipolar	1 (25.0)	51 (21.5)
Bipolar after failed falope	0	4 (1.7)
Laparoscopic Pomeroy	1 (25.0)	1 (0.4)
Converted to laparotomy	0	2 (0.8)
BTL unable to be completed	0	1 (0.4)

1. Percentages of BTL types are based on the number of tubal ligations in the group

Table 3. Complications (percentage listed in parenthesis)

	Pain (n=177)	No Pain (n=237)
Major complications	3 (1.7)	1 (0.4)
Retroperitoneal hematoma from trochar placement	1 (0.6)	0
Bladder dome perforation from trochar placement	1 (0.6)	0
ICU admission for difficult recovery from anesthesia	1 (0.6)	0
Wound infection requiring surgical exploration	0	1 (0.4)
Combined rate of major complications = 1.0%		
Overnight admissions[1]	9 (5.1)	3 (1.3)
Hospital readmission (observation for pain)	1 (0.6)	0

1. Overnight admissions include those listed with major complications, as well those experiencing poor pain control, inability to void, and slow recovery of diet.

◄ IF THIS IS A FINAL REPORT PROCEED TO # 9 ►

7. Protocol Changes:

a. _____ No changes are anticipated and the project will continue as previously approved by the IRB.

b. _____ Changes are anticipated as described below: *(Description……)*

c. When do you anticipate PCSing or separating? Indefinite

8. Protocol Personnel Changes:

Has there been any Principal or Associate Investigator (PI/AI) changes since approval of protocol or the last continuation review? ____ Yes __XX__ No. If yes, complete the following sections (Additions/Deletions). For PI/AI changes, indicate whether or not the IRB approved this change.

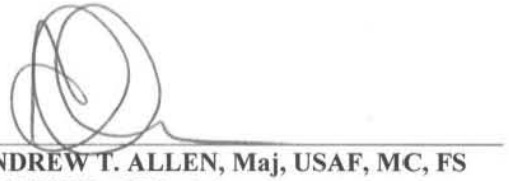
a. Additions: *(Include Name, Protocol function - PI/AI IRB approval - Yes/No)*
b. Deletions: *(Include Name, Protocol function - PI/AI, Effective date of deletion)*

9. Status of Approved Funding: No funding was requested in my original protocol.

10. Publications/Presentations/Awards: N/A

11. Certification of Principal Investigator

My signature certifies that the above titled research has been conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. I understand that a Progress Report is required in order to maintain continuation approval and any changes in the study/methodology must be approved by the IRB prior to implementation. If the study has never been initiated and I am requesting termination (Item 5.c. above), my signature certifies this request. If the study is completed (Items 5.d. & 6.c. above) and I am requesting closure, my signature certifies that the information provided on this form represents an accurate final report.



5 May 2009
Date

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